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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.		
10/591,963	05/15/2007	Howard C Herrmann	UPN-4929	6859		
23377	7590	10/23/2009	EXAMINER			
WOODCOCK WASHBURN LLP CIRA CENTRE, 12TH FLOOR 2929 ARCH STREET PHILADELPHIA, PA 19104-2891				OSINSKI, BRADLEY JAMES		
ART UNIT		PAPER NUMBER				
3767						
MAIL DATE		DELIVERY MODE				
10/23/2009		PAPER				

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/591,963	HERRMANN ET AL.	
	Examiner	Art Unit	
	BRADLEY J. OSINSKI	3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 07 September 2006.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-7 is/are pending in the application.
 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
 5) Claim(s) _____ is/are allowed.
 6) Claim(s) 1-7 is/are rejected.
 7) Claim(s) _____ is/are objected to.
 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on 07 September 2006 is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>7-2-2007</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Drawings

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, first and second lumens and a lumen in which the foldable membrane is advanced through that is not used for cardioplegia must be shown or the feature(s) canceled from the claim(s). Only a single lumen is visible in the figures. No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 1-3 and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckberg et al (5,013,296) in view of Samson et al (6,267,747).

a. Regarding claims 1 and 3, Buckberg discloses a method and device for delivering cardioplegia solution to the coronary arteries including the following steps: Puncturing the ascending aorta between a clamp above the coronary arteries (while not shown, one of ordinary skill in the art would recognize that during antegrade cardioplegia delivery, the clamp would be positioned above the coronary arteries) and the aortic valve (Col.2 lines 51-54 and Col.4 lines 34 and 35) via a coaxial needle 11 inserted through the a lumen 34 of the cannula which is removed after insertion of the cannula (Col.3 lines 37 and 38). The cannula 10 is inserted into the ascending aorta and includes a first lumen 34 for cardioplegia delivery.

While Buckberg substantially discloses the apparatus as claimed, it does not disclose a second lumen adapted to accept a folded non-porous membrane to cover the aortic valve nor the use of such a membrane.

However, Samson discloses an aortic catheter that delivers cardioplegia fluid (Col.5 lines 64-66) but also uses a balloon to occlude blood flow in the aortic

root (Col.6 lines 38 and 39) and prevents the aortic valve from experiencing significant retrograde fluid pressure (Col.11 lines 14-22).The balloon of Samson delivers cardioplegic solution via a porous band of material 126 in the balloon, however, one of ordinary skill in the art would recognize that Buckberg already delivers the cardioplegic solution and thus just a balloon to cover the aortic root/valve but not the coronary ostia is necessary. It is the examiner's position that one of ordinary skill in the art would be able to accomplish this since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. *Nerwin v. Erlicnman*, 168 USPQ 177, 179.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Buckberg to deliver a balloon as taught by Samson to block the aortic root and valve to prevent the aortic root from experiencing significant retrograde fluid pressure.

Additionally, it would have been an obvious matter of design choice to a person of ordinary skill in the art to deliver the balloon via a lumen separate from the main lumen 34 of Buckberg because Applicant has not disclosed that the additional lumen provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with Buckberg because both are used to deliver cardioplegic fluid to the aorta and it has been held that mere duplication of the essential working parts (in this case lumens via which to deliver/withdraw different materials) of a device involves only routine skill in the

art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8. Therefore, it would have been an obvious matter of design choice to modify Buckberg and Samson to obtain the invention as specified in claim(s) 1.

b. Regarding claims 2 and 7, Buckberg discloses the occluder as being a balloon that is in a deflated and then inflated to occlude the blood flow in the aortic root (Col.6 lines 33-39 and Col.8 lines 38-42).

2. Claims 4-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Buckberg et al (5,013,296) and Samson et al (6,267,747) as applied to claim 3 above, and further in view of Makower et al (6,638,293).

c. Regarding claims 4-6, while Buckberg substantially discloses the apparatus as claimed, it does not disclose the membrane being an umbrella that is opened either using a wire or that springs open where both the wire and umbrella are made of nitinol.

However, Makower discloses apparatuses for blocking flow through blood vessels many of them umbrella shaped (figures 4 and 7-9, Col.8 lines 44-48 and Col.1 line 10) structure made of wire and membrane (Col.3 lines 13-15) including nitinol (Col.8 line 65 and Col.9 line 10). The devices may be delivered radially compact such that they self-expand upon delivery (Col.3 line 35) or plastically deformed by application of force or pressure (Col.3 lines 39-42). While Makower does not specifically state the deployment may occur via wire, it does mention linkages to a wire to withdraw the device (Col.3 lines 69-62) via a grab ring (Col.11 lines 26-28). One of ordinary skill in the art would also have knowledge of

the embolic devices that use a wire to apply the necessary force to cause the device to expand (such as by a ring that pivots the wires outwardly).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Samson and Buckberg to replace the balloon of Buckberg with an embolic device such as those taught by Makower to occlude the aortic root and aortic valve as they are both known to occlude blood flow and both are designed to collapse once their use is over.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BRADLEY J. OSINSKI whose telephone number is (571)270-3640. The examiner can normally be reached on M-Th 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571)272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley J Osinski/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767